

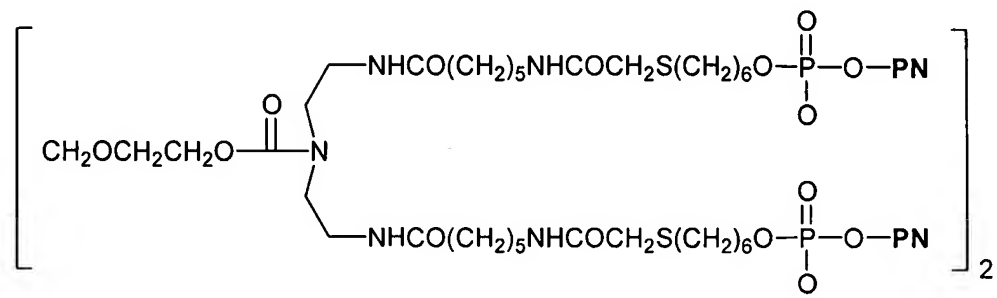
AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A method of stabilizing or improving the health-related quality of life of ~~an~~ a human individual with systemic lupus erythematosus (SLE), comprising administering to the individual an effective amount of a dsDNA epitope which specifically binds to an anti-dsDNA antibody from the individual, wherein the administration of the dsDNA epitope results in a stabilization of or improvement in the individual's health-related quality of life,

wherein administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and

wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is (CA)₁₀•(TG)₁₀ ((SEQ ID NO:2)•(SEQ ID NO:1)),

the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual.

Claim 2 (cancelled)

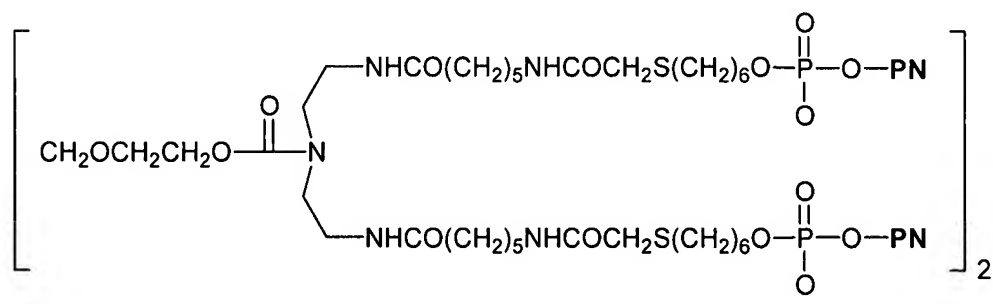
Claim 3 (currently amended): The method of claim [[2]]₁, wherein the sustained reduction is maintained for more than about 16 weeks.

Claim 4 (original): The method of claim 3, wherein the sustained reduction is maintained for at least about 24 weeks.

Claim 5 (currently amended): The method of claim 1, wherein the dsDNA epitope comprises a double-stranded polynucleotide 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1) 5'-TGTGTGTGTGTGTGTGTGTGTG-3' (SEQ ID NO:1) in combination with its complementary strand, or one of the single-stranded polynucleotides 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1) 5'-TGTGTGTGTGTGTGTGTGTGTG-3' (SEQ ID NO:1) or 3'-CACACACACACACACACA-5' (SEQ ID NO:2) 5'-CACACACACACACACACA-3' (SEQ ID NO:2).

Claim 6 (original): The method of claim 1 or claim 5, wherein the dsDNA epitope is administered in the form of a conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more double-stranded DNA (dsDNA) epitopes that specifically bind to an anti-dsDNA antibody from the individual.

Claim 7 (withdrawn-currently amended): The method of claim 6, wherein the conjugate is a compound of the formula

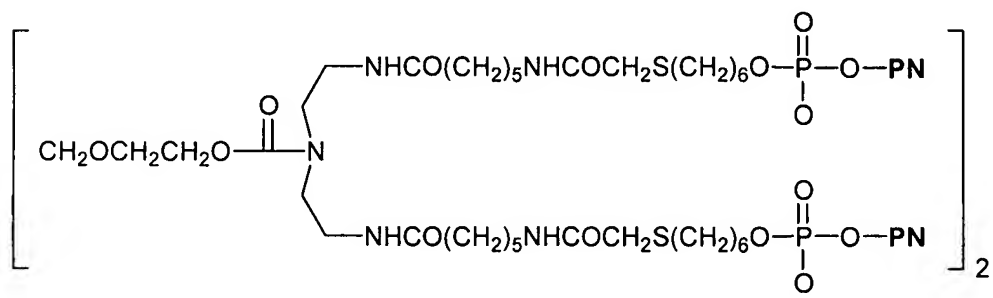


wherein PN is (CA)₁₀•(TG)₁₀•((SEQ ID NO:2)•(SEQ ID NO:1)).

Claim 8 (original): The method of claim 1, wherein the stabilization or improvement in the individual's health-related quality of life occurs following a renal flare.

Claim 9 (original): The method of claim 8, wherein the effective amount of the dsDNA epitope is administered to the individual for a period of more than about 16 weeks.

Claim 10 (withdrawn-currently amended): The method of claim 9, wherein the dsDNA epitope is administered in the form of a compound of the formula



wherein PN is (CA)₁₀•(TG)₁₀•((SEQ ID NO:2)•(SEQ ID NO:1)).

Claim 11 (original): The method of claim 1, wherein the stabilization or improvement in the individual's health-related quality of life is detectable by the Medical Outcome Survey Short Form 36 (SF-36), wherein the stabilization or improvement is reflected in one or more domain scores selected from the group consisting of physical functioning, role physical, bodily pain, general health perception, vitality, social functioning, role emotional, and mental health.

Claim 12 (original): The method of claim 11, wherein the stabilization or improvement in the individual's health-related quality of life is detectable by the Medical Outcome Survey Short Form 36 (SF-36), wherein the stabilization or improvement is reflected in one or more domain scores selected from the group consisting of physical functioning, role physical, bodily pain, general health perception, vitality, social functioning, and mental health.

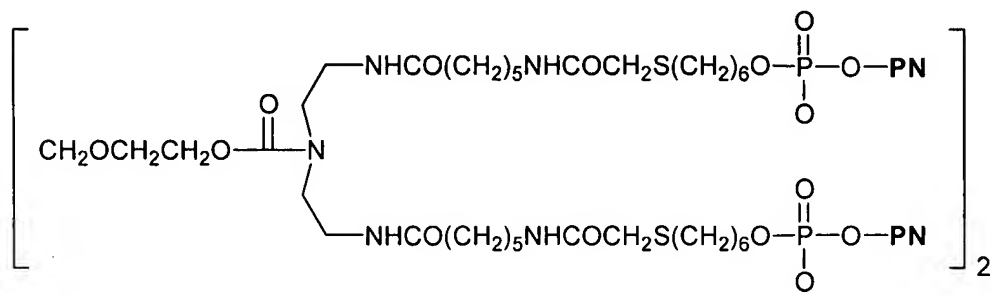
Claim 13 (original): The method of claim 1, which is a method of stabilizing the health-related quality of life of an individual with systemic lupus erythematosus (SLE), wherein the administration of the dsDNA epitope results in a stabilization of the individual's health-related quality of life.

Claim 14 (original): The method of claim 1, which is a method of improving the health-related quality of life of an individual with systemic lupus erythematosus (SLE), wherein the administration of the dsDNA epitope results in an improvement in the individual's health-related quality of life.

Claim 15 (cancelled)

Claim 16 (original): The method of claim 1, wherein the effective amount of the dsDNA epitope is administered to the individual for a period of more than about 16 weeks.

Claim 17 (withdrawn-currently amended): The method of claim 16, wherein the dsDNA epitope is administered in the form of a compound of the formula



wherein PN is $(\text{CA})_{10} \bullet (\text{TG})_{10} \bullet ((\text{SEQ ID NO:2}) \bullet (\text{SEQ ID NO:1}))$.

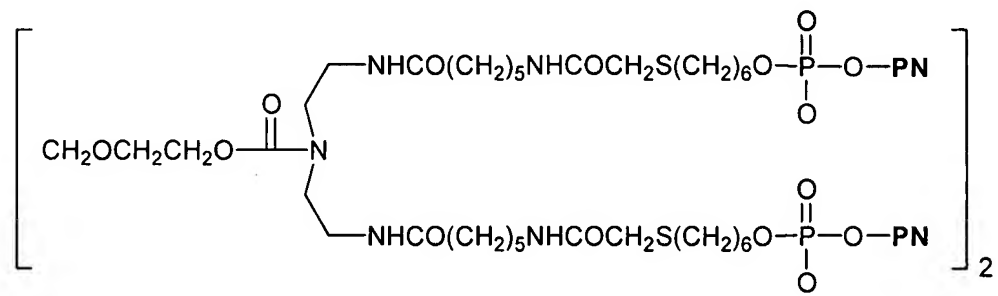
Claims 18-38 (cancelled)

Claim 39 (currently amended): A method of stabilizing or improving the health-related quality of life in ~~an~~ a human individual with SLE comprising the steps of:

- (a) selecting an individual for receiving or continuing to receive treatment based on the individual's need for a stabilized or improved health-related quality of life; and
- (b) administering ~~a treatment~~ an effective amount of a dsDNA epitope to the selected individual,

wherein administration of the ~~treatment effects~~ dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and

wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is (CA)₁₀•(TG)₁₀ ((SEQ ID NO:2)•(SEQ ID NO:1)),

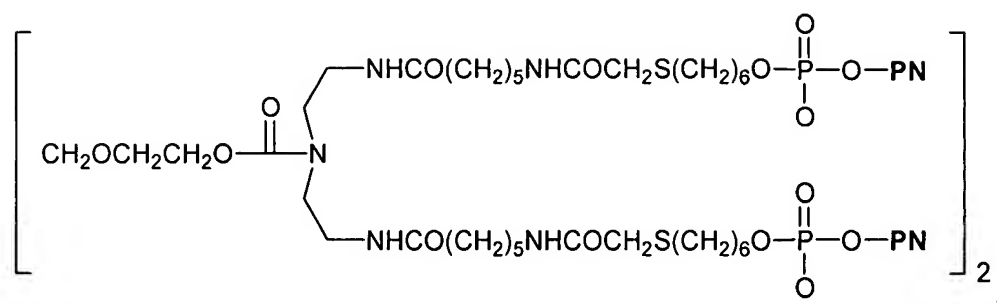
the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual.

Claim 40 (currently amended): A method of stabilizing or improving the health-related quality of life in ~~an~~ a human individual having SLE comprising the steps of:

- (a) selecting an individual to receive or continue to receive a dsDNA epitope based on the affinity of the dsDNA epitope for an anti-dsDNA antibody in the individual; and
- (b) administering an effective amount of the dsDNA epitope to the selected individual, wherein administration of the dsDNA epitope stabilizes or improves the health-related quality of life in an individual,

wherein administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month,
and

wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is (CA)₁₀•(TG)₁₀((SEQ ID NO:2)•(SEQ ID NO:1)),

the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual.

Claim 41 (new): The method of claim 1, wherein if the dsDNA epitope is administered weekly in the form of the conjugate, the administration of the composition comprises administering a dose of about 5 mg/kg to about 100 mg/kg of the conjugate to the individual.

Claim 42 (new): The method of claim 1, wherein if the dsDNA epitope is administered weekly in the form of the conjugate, the administration of the composition comprises administering a dose of about 10 mg/kg or higher of the conjugate to the individual.

Claim 43 (new): The method of claim 1, wherein the sustained reduction is at least about 20% below baseline.

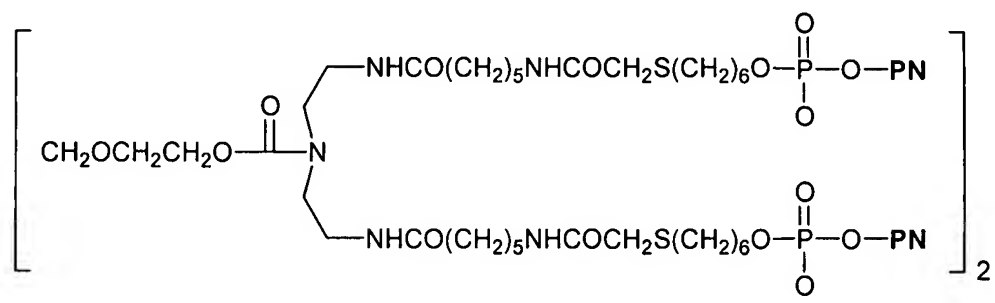
Claim 44 (new): The method of claim 43, wherein the sustained reduction is at least about 30% below baseline.

Claim 45 (new): A method of stabilizing or improving the health-related quality of life of a human individual with systemic lupus erythematosus (SLE), comprising administering to the individual an effective amount of a dsDNA epitope which specifically binds to an anti-dsDNA antibody from the individual,

wherein the administration of the dsDNA epitope results in a stabilization of or improvement in the individual's health-related quality of life,

wherein the administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and

wherein if the dsDNA epitope is administered weekly to the individual in the form of a conjugate of the formula



wherein PN is (CA)₁₀•(TG)₁₀ ((SEQ ID NO:2)•(SEQ ID NO:1)),

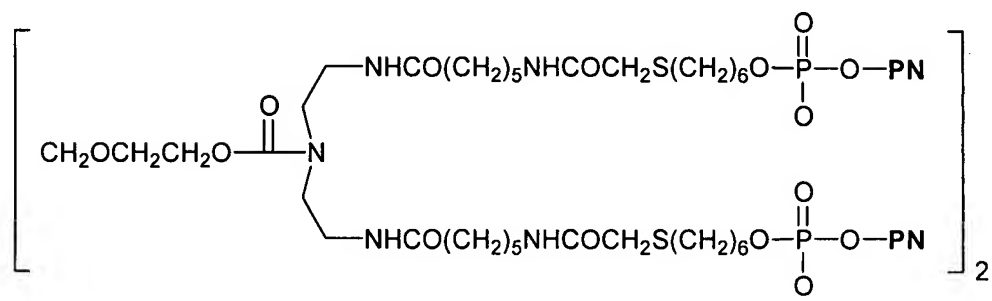
the dsDNA epitope is administered weekly to the individual for a period of more than about 16 consecutive weeks.

Claim 46 (new): The method of claim 45, wherein the sustained reduction is maintained for more than about 16 weeks.

Claim 47 (new): The method of claim 1, wherein the dsDNA epitope comprises a double-stranded polynucleotide 5'-TGTGTGTGTGTGTGTGTGTG-3' (SEQ ID NO:1) in combination with its complementary strand, or one of the single-stranded polynucleotides 5'-TGTGTGTGTGTGTGTGTGTG-3' (SEQ ID NO:1) or 5'-CACACACACACACACACACA-3' (SEQ ID NO:2).

Claim 48 (new): The method of claim 45 or 47, wherein the dsDNA epitope is administered in the form of a conjugate comprising (a) a non-immunogenic valency platform molecule and (b) two or more double-stranded DNA (dsDNA) epitopes that specifically bind to an anti-dsDNA antibody from the individual.

Claim 49 (new): The method of claim 48, wherein the conjugate is a compound of the formula



wherein PN is (CA)₁₀•(TG)₁₀ ((SEQ ID NO:2)•(SEQ ID NO:1)).

Claim 50 (new): The method of claim 45, wherein the stabilization or improvement in the individual's health-related quality of life is detectable by the Medical Outcome Survey Short Form 36 (SF-36), wherein the stabilization or improvement is reflected in one or more domain scores selected from the group consisting of physical functioning, role physical, bodily pain, general health perception, vitality, social functioning, and mental health.

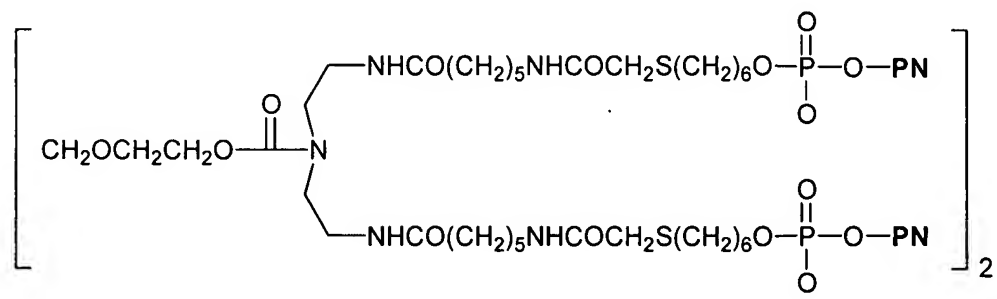
Claim 51 (new): The method of claim 45, wherein the sustained reduction is at least about 20% below baseline.

Claim 52 (new): The method of claim 51, wherein the sustained reduction is at least about 30% below baseline.

Claim 53 (new): The method of claim 6, wherein if the dsDNA epitope is administered weekly in the form of the conjugate, the administration of the composition comprises administering a dose of about 5 mg/kg to about 100 mg/kg of the conjugate to the individual.

Claim 54 (new): The method of claim 6, wherein if the dsDNA epitope is administered weekly in the form of the conjugate, the administration of the composition comprises administering a dose of about 10 mg/kg or higher of the conjugate to the individual.

Claim 55 (new): A method of stabilizing or improving the health-related quality of life of a human individual with systemic lupus erythematosus (SLE), comprising administering to the individual an effective amount of a composition comprising a conjugate of the formula



wherein PN is (CA)₁₀•(TG)₁₀ ((SEQ ID NO:2)•(SEQ ID NO:1)),

wherein the administration of the composition results in a stabilization of or improvement in the individual's health-related quality of life,

wherein administration of the composition results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and

wherein if the composition is administered to the individual weekly, a dose of about 3 mg/kg or higher of the conjugate is administered weekly to the individual.

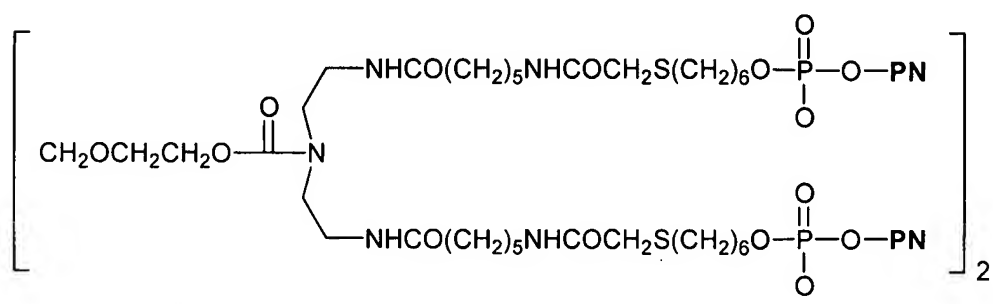
Claim 56 (new): The method of claim 55, wherein if the composition is administered to the individual weekly, a dose of about 5 mg/kg to about 100 mg/kg of the conjugate is administered weekly to the individual.

Claim 57 (new): The method of claim 55, wherein if the composition is administered to the individual weekly, a dose of about 10 mg/kg or higher of the conjugate is administered weekly to the individual.

Claim 58 (new): The method of claim 55, wherein if the composition is administered to the individual weekly, a dose of about 200 mg to about 500 mg of the conjugate is administered weekly to the individual.

Claim 59 (new): The method of claim 55, wherein the administration of the composition comprises administering a dose of about 300 mg of the conjugate to the individual.

Claim 60 (new): A method of stabilizing or improving the health-related quality of life of a human individual with systemic lupus erythematosus (SLE), comprising administering to the individual an effective amount of a composition comprising a conjugate of the formula



wherein PN is (CA)₁₀•(TG)₁₀ ((SEQ ID NO:2)•(SEQ ID NO:1)),

wherein the administration of the composition results in a stabilization of or improvement in the individual's health-related quality of life,

wherein administration of the composition results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and

wherein if composition is administered weekly to the individual, the composition is administered weekly to the individual for a period of more than about 16 consecutive weeks.